

10/589866

IAP14 Rec'd PCT/PTO 18 AUG 2006

CLAIMS:

1-65 (canceled)

66. (new) An amino acid molecule comprising a peptide comprising at least one of the following characteristics:

- (a) being capable binding to ManLAM binding antibodies; and
- (b) being capable of eliciting, upon immunization in a subject, production of ManLAM-binding antibodies.

67. (new) The amino acid molecule of Claim 66, wherein said ManLAM binding antibodies are anti-ManLAM antibodies.

68. (new) The amino acid molecule of Claim 66, wherein said ManLAM binding antibodies are monoclonal antibodies (mAbs).

69. (new) The amino acid molecule of Claim 68, wherein said mAbs are CS40 antibodies.

70. (new) The amino acid molecule of Claim 66, which does not bind to antibodies directed against lipoglycans selected from non-mannosylated and low mannosylated lipoglycans.

71. (new) The amino acid molecule of Claim 70, which does not bind to CS35 anti-LAM mAb, 735 anti-ploy $\alpha(2\rightarrow8)$ N-acetyl neuraminic acid mAb, and 2H1 anti- glucuronoxylomannan mAb.

72. (new) The amino acid molecule of Claim 66, wherein said peptide has an internal aromatic amino acid residue.

73. (new) The amino acid molecule of Claim 72, wherein said aromatic amino acid residue is selected from Phenylalanine (F), Histidine (H), Tryptophan (W), Tyrosine (Y) and conservative substitutions thereof.

74. (new) The amino acid molecule of Claim 72, wherein said peptide comprises a hydrophilic amino acid residue adjacent and preceding said aromatic residue.

75. (new) The amino acid molecule of Claim 72, wherein said aromatic residue is W.

76. (new) The amino acid molecule of Claim 66, wherein said peptide comprises the sequence selected from:

ISLTEWSMWYRH (SEQ ID NO:1);

EEGPWSTHVGRT (SEQ ID NO:2);

WGNEGGDHLQPV (SEQ ID NO:3);

SLKIRWELKMYQE (SEQ ID NO:4);

AVERWEKHTWSE (SEQ ID NO:5);

and immunologic modifications thereof.

77. (new) The amino acid molecule of Claim 66, wherein said peptide comprises the sequence ISLTEWSMWYRH (SEQ ID NO:1), or an immunogenic modification thereof.

78. (new) A method for diagnosing a mycobacterial infection in a subject the method comprising:

(a) contacting said sample with an amino acid molecule comprising a peptide comprising at least one of the following characteristics:

i) being capable of binding to ManLAM-binding antibodies, and

ii) being capable of eliciting, upon immunization in a subject, production of ManLAM binding antibodies; and

(b) determining formation of a complex comprising said amino acid molecule and ManLAM binding antibodies, if present in the sample,

wherein a positive determination indicates mycobacterial infection in the subject.

79. (new) A method for determining whether a subject has active mycobacterial infection the method comprising:

- (a) contacting a sample from said subject with an amino acid molecule comprising a peptide comprising at least one of the following characteristics:
 - i) being capable of binding to ManLAM-binding antibodies, and
 - ii) being capable of eliciting, upon immunization in a subject, production of ManLAM binding antibodies;
 - (b) determining level of complexes comprising said amino acid molecule and ManLAM binding antibodies; and
 - (c) comparing said level to a standard,
- wherein a level higher than the standard indicates active myobacterial infection in the subject.

80. (new) A method for determining treatment efficacy in a subject having a mycobacterial infection, the method comprising:

- (a) contacting samples from said subject, from at least two discrete time points, with an amino acid molecule comprising a peptide comprising at least one of the following characteristics:
 - i) being capable of binding to ManLAM-binding antibodies, and
 - ii) being capable of eliciting, upon immunization in a subject, production of ManLAM binding antibodies; and
 - (b) determining level of complexes comprising said amino acid molecule and ManLAM binding antibodies in said samples,
- wherein a difference in the level between the two time points is indicative of the effectiveness of the treatment.

81. (new) A kit for diagnosing mycobacterial infection in a subject comprising an amino acid molecule comprising a peptide, the peptide comprising at least one of the following characteristics:

- (a) being capable of binding to ManLAM-binding antibodies; and
- (b) being capable of eliciting production of ManLAM binding antibodies.

82. (new) A vaccine comprising an immunologically acceptable carrier and as an active agent an amino acid molecule comprising a peptide comprising at least one of the following characteristics:

- (a) being capable of binding to ManLAM-binding antibodies; and
- (b) being capable of eliciting, upon immunization of a subject, production of ManLAM binding antibodies.

83. (new) The vaccine of Claim 82, wherein said ManLAM binding antibodies are anti-ManLAM antibodies.

84. (new) The vaccine of Claim 83, wherein the amino acid molecule does not bind to antibodies directed against lipoglycans selected from non-mannosylated and low mannosylated lipoglycans.

85. (new) The vaccine of Claim 84, which amino acid molecule does not bind to CS35 anti-LAM mAb, 735 anti-ploy $\alpha(2\rightarrow8)$ N-acetyl neuraminic acid mAb, and 2H1 anti- glucuronoxylomannan mAb.

86. (new) The vaccine of Claim 83, wherein said amino acid molecule comprises at least one peptide having an internal aromatic amino acid residue.

87. (new) The vaccine of Claim 86, wherein said aromatic amino acid residue is selected from Phenylalanine (F), Histidine (H), Tryptophan (W), Tyrosine (Y) and conservative substitutions thereof.

88. (new) The vaccine of Claim 86, wherein said peptide comprises a hydrophilic amino acid residue adjacent and preceding said aromatic residue.

89. (new) The vaccine of Claim 88, wherein said aromatic residue is W.

90. (new) The vaccine of Claim 83, wherein said amino acid molecule comprises at least one peptide having the sequence selected from:

- ISLTEWSMWYRH (SEQ ID NO:1);
- EEGPWSTHVGRT (SEQ ID NO:2);
- WGNEGDDLQPV (SEQ ID NO:3);
- SLKIRWELKMYQE (SEQ ID NO:4);

AVERWEKHTWSE (SEQ ID NO:5);

and immunologic modifications thereof.

91. (new) The vaccine of Claim 83, wherein amino acid comprises a peptide having the sequence ISLTEWSMWYRH (SEQ ID NO:1), and immunologic modifications thereof.
92. (new) A method of immunization of a subject against mycobacterial infection, the method comprises providing said subject with an immunizing amount of an amino acid molecule comprising a peptide comprising at least one of the following characteristics:
- (a) being capable of binding to ManLAM-binding antibodies; and
 - (b) being capable of eliciting, upon immunization of a subject, production of ManLAM binding antibodies.
93. (new) The method of Claim 92, wherein the amino acid molecule does not bind to antibodies directed against lipoglycans selected from non-mannosylated and low mannosylated lipoglycans.
94. (new) The method of Claim 93, wherein the amino acid molecule does not bind to CS35 anti-LAM mAb, 735 anti-ploy $\alpha(2\rightarrow8)$ N-acetyl neuraminic acid mAb, and 2H1 anti- glucuronoxylomannan mAb.
95. (new) The method of Claim 94, wherein said amino acid molecule comprises at least one peptide having an internal aromatic amino acid residue.
96. (new) The method of Claim 95, wherein said aromatic amino acid residue is selected from Phenylalanine (F), Histidine (H), Tryptophan (W), Tyrosine (Y) and conservative substitutions thereof.
97. (new) The method of Claim 95, wherein said peptide comprises a hydrophilic amino acid residue adjacent and preceding said aromatic residue.
98. (new) The method of Claim 95, wherein said aromatic residue is W.
99. (new) The method of Claim 93, wherein said amino acid molecule comprises at least one peptide having the sequence selected from:

ISLTEWSMWYRH (SEQ ID NO:1);
EEGPWSTHVGRT (SEQ ID NO:2);
WGNEGGDHLQPV (SEQ ID NO:3);
SLKIRWELKMYQE (SEQ ID NO:4);
AVERWEKHTWSE (SEQ ID NO:5);

and immunologic modifications thereof.

100. (new) The method of Claim 99, wherein the amino acid molecule comprises a peptide having the sequence ISLTEWSMWYRH (SEQ ID NO:1), and immunologic modification thereof.